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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,664	08/09/2001	Dan W. Denney JR.	GENTIOPE-06499	3389
23535	7590	10/26/2005	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/925,664

Applicant(s)

DENNEY, DAN W.

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

#### **RE: Denney DW**

1. Upon further review and reconsideration, the finality of the previous Office action is hereby withdrawn pursuant. Applicant's first submission after final filed on 4/8/2005 has been entered.
2. Claims 1-20 and 27-32 are canceled without prejudice or disclaimer.
3. Claims 21-26 are pending and examined on the merits.
- 4.

#### ***Claim Rejections Withdrawn - 35 U.S.C. § 112, 1<sup>st</sup> paragraph***

5. The rejection of claims 21-26 under 35 USC § 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is withdrawn in view of the persuasive arguments and amendments set forth by the applicant in the paper filed on 4/8/2005.

#### ***New Arguments***

##### ***Priority***

6. The claims of the instant invention claim priority to the earlier filed application 08/644,664, now US Patent 5,776,746. However the earlier filed application does not support the limitation of a multivalent composition comprising at least two heavy chain variable regions derived from the B-cell lymphoma cells wherein the heavy chain variable regions differ by at least one idiotope. As such, the priority date of the instant application has been afforded the filing date of the divisional application 08/761277, now

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US Patent 5,972,334. As such, the date of 12/06/1996 will be used for the determination of prior art.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Moreckie *et al* (Cancer Immunol. Immunother. Oct. 1995; 41(4):236-242).

Moreckie *et al* teach the administration of irradiated B-cell leukemia/lymphoma cells to a subject. Moreover, Moreckie *et al* also teach that the B-cell leukemia/lymphoma cells were capable of generating an immune response (see page 237). Given the broadest reasonable interpretation of the claims, the multivalent composition of the instant invention reads on a B-cell lymphoma cell comprising on its surface multiple heavy chain variable regions that differ by at least one idio type. Moreover, the limitation of "recombinant" is viewed as a process by which the product is made and is given little patentable weight unless the applicant can establish that the product is structurally different or distinct from that already taught in the prior art. In the absence of objective evidence the contrary, the B-cell tumor cells would in fact express on its surface multiple idiotypic distinct heavy chains.

***Claim Rejections - 35 USC § 103***

9. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moreckie *et al* (previously cited) in view of Kaminski *et al* (J. Immunol 1987; 138(4):1289-1296) and Gupta *et al* (Vaccines 1995; 13(14): 1263-1276).

a. The teachings of Moreckie *et al* as they apply to claims 21-22 have been set forth above.

b. Moreckie *et al* do not specifically teach the combination of a B-cell lymphoma cell and either adjuvants or carrier proteins.

c. Kaminski *et al* teach the use of a carrier protein, KLH for generation of an tumor immunity response when an Id protein was administered for the intent of treating B-cell lymphoma. In addition, Kaminski *et al* also teaches the co-administration of adjuvants (see page 1290, for example)

d. Gupta *et al* provides a review of adjuvants and the use of adjuvants for the amplification of an immune response for compositions intended for immune response generation. Specifically, Gupta *et al* teaches the use of SAF-1 (see page 1264 for example).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine adjuvants, such as SAF-1, and carrier proteins, such as KLH for the generation of an immune response against a B-cell lymphoma because the combination of Moreckie *et al*, Kaminski *et al* and Gupta *et al* taught the claimed invention as a whole. One of ordinary skill in the art would have been motivated to combine the different components for the treatment of B-cell lymphoma

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because each were taught separately to be effect for the elicitation of an tumor specific immune response against B-cell lymphoma. One of skill in the art would have known to use SAF-1 in place of Freund's adjuvant as taught by Kaminski *et al* because the use of adjuvants was well known and practiced in the art as exemplified by Gupta *et al*.

Therefore, the invention as a whole was obvious.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1643  
October 14, 2005

  
**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**